IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VYTACERA BIO, LLC,	:	
Plaintiff,	:	
v.	:	C.A. No. 20-333-LPS-CJB
CYTOMX THERAPEUTICS, INC.,	:	
Defendant.	:	

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a Report and Recommendation (D.I. 130) on October 7, 2021, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent Nos. 8,809,504 (the "'504 patent") and 9,775,913 (the "'913 patent");

WHEREAS, on October 28, 2021, Plaintiff Vytacera Bio, LLC ("Vytacera" or "Plaintiff") objected to that Report (D.I. 141), asserting that it incorrectly construed the terms "inhibitor" and "inhibitor is administered alone or together with said antibody;"

WHEREAS, on November 16, 2021, Defendant CytomX Therapeutics, Inc. ("CytomX" or "Defendant") responded to those Objections (D.I. 145);

WHEREAS, Magistrate Judge Burke issued another Report and Recommendation (D.I. 149) on March 10, 2022, recommending that the Court adopt a certain claim construction for the disputed term "recognition domain" in the '504 and '913 patents;

WHEREAS, on April 7, 2022, CytomX objected to that Report (D.I. 151);

WHEREAS, on April 27, 2022, Vytacera responded to those Objections (D.I. 154);

WHEREAS, the Court has considered the parties' objections and responses *de novo*, *see St. Clair Intell. Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l)(C); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that (i) Vytacera's Objections (D.I. 141) to Judge Burke's recommended constructions of "inhibitor" and "inhibitor is administered alone or together with said antibody" are **OVERRULED** and the constructions set forth in the Report (D.I. 130) are **ADOPTED**; and (ii) CytomX's Objections (D.I. 151) to Judge Burke's recommended construction of "recognition domain" are **OVERRULED** and the construction set forth in the Report (D.I. 149) is **ADOPTED**.

1. Vytacera objects to the recommended construction of "inhibitor" as meaning "a molecule, separate from the [biologically active agent/antibody], having the ability to bind, inhibit, suppress, neutralize, or decrease activity of a [biologically active agent/antibody]." (D.I. 141 at 2-9) This construction resolved the parties' dispute as to whether the inhibitor can ever be part of the same molecule as the biologically active agent ("BAA"). (*See* D.I. 130 at 6) Relying on both the claim language and the patents' shared specification, the Report concluded that the inhibitor and the BAA must always be separate molecules. (*See id.*) The Court agrees. Notably, the claims describe the inhibitor as having a component that takes an action – for example, binding, inhibiting, or suppressing – that affects the BAA, which would indicate to a person of ordinary skill in the art that the inhibitor and BAA are distinct entities.[1] (*See* '504 patent cl. 1) As the Report states, "[i]t is hard to conceive of how a first entity (the inhibitor) could be said to

[1] In the '913 patent, the "biologically active agent" is an "antibody." ('913 patent cls. 1, 22) There is no dispute that the "antibody" of the '913 patent is a "biologically active agent" as described in the patents, and the Court's analysis applies equally to the claims of both patents. (*See* D.I. 130 at 6 n.3, 7)

'inhibit' . . . a second entity (the biologically active agent), if those two things were actually all part of the same chemical molecule." (D.I. 130 at 7) The specification provides further support. The patents' Abstract explains that "[t]he invention relates to molecules inhibiting biologically active compounds" ('504 patent, Abstract), echoing the claim language and suggesting, again, that inhibitors are distinct from BAAs. The specification also describes the "[i]nhibitor-ligand pair" (with "ligand" used interchangeably with "BAA") as a "***set*** of molecules," indicating that the inhibitor and ligand (i.e., the BAA) are not part of the same molecule. (*Id.* at 5:36-37, 45-47) Additionally, the Court finds nothing in the claims or the specification that suggests the inhibitor and BAA are chemically attached in the same molecule. (*See* D.I. 130 at 7-8)

2. As CytomX notes, Vytacera's Objections have little to do with Judge Burke's actual analysis. (*See* D.I. 145 at 1) They do not, for example, raise any specific issues with the Report's reliance on the claim language or specific portions of the specification to support its constructions. (*See id.*) Having considered the arguments Vytacera ***does*** raise, the Court finds none of them persuasive.

3. First, Vytacera argues the patents' specification teaches that the claimed inhibitor and BAA can be a "unitary molecule." (*See* D.I. 141 at 2-4) As an initial matter, the Court agrees with CytomX that Vytacera has waived this argument, as it is raised for the first time in connection with its Objections and conflicts with its position before Judge Burke, where Vytacera agreed that the claimed inhibitor and BAA are "distinct molecules." (*See* D.I. 145 at 5) (citing D.I. 136 at 15) Vytacera has not shown good cause for raising this new, and inconsistent, argument at this stage.[2] In any event, Vytacera's argument also fails on the merits. Vytacera

[2] In its Certification pursuant to the Court's October 9, 2013 Standing Order for Objections Filed Under Fed. R. Civ. P. 72, Plaintiff states that it has good cause to bring these new arguments because they "are related solely to points and comments discussed during the August 23, 2021

appears to argue that the specification's disclosure of molecules – for example, a catalytic antibody – that can serve as either an inhibitor or a BAA amounts to a disclosure that a single "unitary" molecule can simultaneously serve those two roles. (*See id.* at 5-6) The Court agrees with CytomX, however, that the disclosure of such molecules provides no basis to conclude that the claimed inhibitor and BAA are a "unitary molecule." (*See id.* at 6) ("Put simply, that a certain type of molecule can possibly serve either of two roles (i.e., BAA or inhibitor) does not answer whether, as a matter of claim construction, a single 'unitary' molecule can simultaneously serve those two roles in the ***claimed*** invention.")

4. Vytacera's reliance on the patents' specification to argue that the claimed inhibitor and BAA can be chemically attached is equally unsuccessful. The Court agrees with CytomX that the term "operably linked" describes the connection between the inhibitor's first and second moieties – not a connection between the inhibitor and the BAA. (*See id.* at 7) Next, Vytacera points to a preferred embodiment in which the active agent or active compound (both purportedly interchangeable with BAA) can include a cytotoxic protein. (D.I. 141 at 5) (citing '504 patent at 7:48-50, 8:60-66) Since covalent attachment (or a chemical union) can be accomplished by such a protein, Vytacera argues this preferred embodiment provides further support for the notion that the claimed inhibitor and BAA can be chemically attached. (*Id.* at 4-5) Vytacera also points to another portion of the specification discussing "a post-cleavage cytotoxic agent derivative" that can be attached to a linker unit, which can also accomplish covalent attachment. (*See id.*) (citing '504 patent at 31:11-15) As CytomX notes, however, that passage never refers to the referenced cytotoxic agent as a BAA; nor does the passage speak to

Markman hearing." The Court is not persuaded by this assertion. Moreover, Vytacera fails to identify the new arguments it advances – as required by the Standing Order – placing the burden on Defendant and the Court to do so. (*See* D.I. 145 at 9 n.5)

the relationship between the claimed ***inhibitor*** and the BAA. (*See* D.I. 145 at 7-8) The Court agrees with CytomX that these "cherry-picked" excerpts from the specification do not provide significant support for Vytacera's position. (*See id.*)

5. Vytacera next faults the Report for not including the claimed second moiety in its construction of "inhibitor." (*See* D.I. 141 at 6-7) There is no dispute, however, that the inhibitor must have a second moiety. (*See* D.I. 145 at 8) ("CytomX does not contest that the inhibitor, as construed, must meet the additional limitations of the claims, which require first and second moieties.") Judge Burke's construction did not "ignore" the role of the inhibitor's second moiety; rather, it reasonably did not address this uncontested point.

6. Vytacera contends that expert testimony is required to determine whether the claimed "inhibitor" and BAA are chemically attached, and the Court should therefore return this matter to Judge Burke to reopen claim construction after expert discovery. (*See* D.I. 141 at 7-8) As CytomX points out, however, "Vytacera had every opportunity to present expert testimony according to the deadlines set by the Scheduling Order and chose not to do so." (D.I. 145 at 9) Nor did Judge Burke request expert testimony or supplemental briefing after the claim construction hearing. The Court agrees with CytomX and the Report that the intrinsic evidence was sufficient to resolve the parties' dispute. (*See id.*)[3]

7. Vytacera argues CytomX's proposed construction invited improper validity and infringement analysis at this stage, pointing to CytomX's reference to its accused product during the *Markman* hearing. (D.I. 141 at 8-9) But CytomX's passing reference to its accused product falls far short of an admission that its addition of the "separate" limitation to its construction was "never centered on the claims," as Vytacera alleges. (*Id.* at 9) There is no evidence Judge Burke

[3] Moreover, this, too, is a new argument and waived.

relied on CytomX's accused technology in construing the claim terms; indeed, the record reflects his understanding that CytomX's technology "has no relevance to the claim construction process." (D.I. 136 at 12; *see also* D.I. 145 at 9 n.4)

8. Vytacera also objects to the recommended construction of "inhibitor is administered alone or together with said antibody" as meaning "inhibitor is administered by itself, i.e., not with said antibody, or inhibitor is co-administered with said antibody." (D.I. 141 at 9-10) Vytacera points to the Report's reference to this dispute as an "offshoot" of the dispute over the "inhibitor" term, arguing the Court should reject the Report's construction of this term for the same reasons as discussed in connection with the first term. (*Id.* at 9) Accepting Plaintiff's own logic, the Court rejects Plaintiff's arguments, for all of the reasons discussed above in connection with the "inhibitor" term. Moreover, the Court agrees with Judge Burke's analysis as to the administration of the inhibitor and the BAA, which Vytacera does not directly challenge despite it being central to Judge Burke's construction.[4] (*See* D.I. 130 at 10-11)

9. The Court now turns to Defendant's Objections. CytomX objects to the recommended construction of "recognition domain" ("RD") as meaning "targeting moiety, i.e. a molecule that binds to a defined population of cells." (*See* D.I. 151 at 6-10) As to this term, the parties' sole dispute is whether the RD recited in certain dependent claims must be a "distinct

[4] Vytacera's Objections focus on the Report's construction of the two terms already discussed. Vytacera adds in a footnote that "the aforementioned arguments overlap and are applicable to all *Markman* terms," so the Court should reject the Report's constructions of two other terms as well. (D.I. 141 at 9 n.3) Vytacera has offered no separate analysis as to these other two terms. This footnote – which CytomX describes as a "throw-away effort to impugn the otherwise uncontested recommended constructions" (D.I. 145 at 10 n.6) – is far from adequate to obtain the relief sought. Moreover, if Vytacera is correct that the terms all overlap, then the Court would reach the same conclusion (i.e., agree with the Report) with respect to all of the terms. Hence, to be clear, the Court adopts the Report's recommended constructions of "reduction of binding activity of said inhibitor" and "biologically active agent."

molecular component" from the BAA and the inhibitor. (*See id.* at 1) As the Report explains, both parties agree a RD can be part of the same molecule as either a BAA or an inhibitor. (D.I. 149 ¶ 3) CytomX, however, seeks a construction that would require that the RD must also be a "distinct molecular component" from the BAA and the inhibitor. The Court agrees with the Report that CytomX has failed to justify the narrow construction it seeks, for reasons including its failure to provide persuasive support for the concept of "intra-molecule distinctness" it proposes. (*See id.* ¶ 4)

10. CytomX lodges three primary complaints with the Report's reasoning as to this term. First, it argues the Report made an error of law by "start[ing] with an apparent presumption that two or more claim elements can be indistinct." (D.I. 151 at 6) The Court disagrees. Judge Burke simply observed that, although the RD has a different name than "inhibitor" and "BAA," and although the patents indicate it has a distinct function, this does not compel a conclusion that it must always be a "distinct molecular component" from those other components. (*See* D.I. 149 ¶ 4) The Report does not rely on any presumption of indistinctness; rather, it acknowledges certain distinctions between the RD and other claim elements, but finds the particular distinction advocated by CytomX unsupported and somewhat confusing. (*See id.*) (noting "[t]his concept of 'intra-molecule distinctness' does not appear to be discussed in the patents-in-suit in any clear, direct way" and it is unclear "what it actually means to be a 'distinct molecular component'")

11. Second, CytomX contends that the Report's recommended construction is at odds with the claims and specification, which purportedly support CytomX's argument that the inhibitor, BAA, and RD are "distinct molecular components." (*See* D.I. 151 at 7-9) As the Court already explained, however, the claims' use of different language for and assignment of

different functions to the three claim elements does not compel the construction CytomX seeks. Nor does the specification. CytomX points to preferred embodiments describing the RD as having a discrete function from the BAA or inhibitor or as having an "association" with those other elements (*see id.* at 7-8), but the Court agrees with Vytacera that these examples do not foreclose the possibility that those elements could be indistinct (*see* D.I. 154 at 7). Moreover, as Vytacera notes, the record lacks any explicit disclaimer of an embodiment in which the RD and BAA are indistinct. (*See id.* at 3)[5]

12. Third, CytomX asserts that its proposed construction is consistent with Judge Burke's other recommended constructions (and that Vytacera's is not). (*See* D.I. 151 at 9-10) For example, referencing dependent claim 16 of the '913 patent, CytomX argues Vytacera's construction would allow "the BAA (in the guise of a 'recognition domain') to be attached to the inhibitor," which would "plainly violate[] the recommended 'inhibitor construction.'" (*Id.* at 10) But the Court agrees with the Report that this example does not "necessarily mean[] that a RD could never, under any circumstance, be seen as indistinguishable molecularly from a BAA." (D.I. 149 ¶ 5) As the Report concludes, CytomX has not justified importing its particular conception of distinctness into the specification's express definition of RD, which the Report's recommended construction reflects. (*See id.* ¶ 1) ("The recommended construction . . . comes from an explicit definition of the RD term in the patents.") (citing '504 patent at 6:5-7)

[5] The Court finds it unnecessary, given its other conclusions, to consider Plaintiff's expert's declaration, or Defendant's contention that it was untimely. The Report likewise found it unnecessary to do so.

13. Given the detailed reasoning provided in the Reports, it is unnecessary to address the parties' Objections any further.

May 9, 2022
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES CIRCUIT JUDGE